

**REMARKS**

Applicants acknowledge receipt of the Office Action mailed January 11, 2010.

In the Office Action<sup>1</sup>, the Examiner objected to the drawings; objected to claim 3; rejected claims 10-13, 15, 17, 19-23, and 39 under 35 U.S.C. § 112, first paragraph; rejected claims 38 and 39 under 35 U.S.C. § 112, second paragraph; rejected claims 1, 3, 5, 7, and 9 under 35 U.S.C. § 103(a) as being unpatentable over *Morita* (U.S. Patent No. 5,730,753) in view of *Abulhaj et al.* ("*Abulhaj*") (U.S. Patent No. 6,852,119); rejected claim 8 under 35 U.S.C. § 103(a) as being unpatentable over *Morita* in view of *Abulhaj*, and further in view of *Duchon et al.* ("*Duchon*") (U.S. Patent No. 5,964,718); rejected claims 10-12 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert et al.* ("*Hofert*") (U.S. Patent No. 4,203,446); rejected claims 13, 15, 19, and 21-23 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert* in view of *Morita*, and further in view of *Abulhaj*; and rejected claim 20 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert* in view of *Morita* and *Abulhaj*, and further in view of *Duchon*.

By this Amendment, Applicants amend claims 1, 3, 10, 13, 38, and 39. Upon entry of this Amendment, claims 1, 3, 5, 7-13, 15, 17, and 19-39 will remain pending, with claims 24-37 withdrawn from consideration. Of the claims under examination, claims 1, 10, and 13 are independent.

The originally-filed specification, claims, abstract, and drawings fully support the amendments to claims 1, 3, 10, 13, 38, and 39. No new matter has been introduced.

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<sup>1</sup> The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

Based on the foregoing amendments and the arguments that follow, Applicants traverse the objections and rejections above and respectfully request reconsideration for at least the reasons that follow.

**I. OBJECTION TO THE DRAWINGS**

The drawings stand objected to under 37 C.F.R. § 1.83(a) because the drawings must show every feature of the invention specified in the claims. See Office Action, p. 4. Specifically, the Examiner alleges, “the limitation found in claim[s] 10 and 13 that the one or more spring surfaces of the lancet holder engages both the internal compression spring and the external compression spring must be shown or the feature(s) canceled from the claim(s).” *Id.* Although Applicants do not necessarily agree with the Examiner, Applicants have amended claims 10 and 13 in an effort to expedite prosecution. Applicants therefore request that the objection to the drawings be withdrawn.

**II. 35 U.S.C. § 112, FIRST PARAGRAPH, REJECTION**

Claims 10-13, 15, 17, 19-23, and 39 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. See Office Action, p. 5. Specifically, the Examiner alleges, “[c]laims 10 and 13 recite ‘the one or more spring surfaces of the lancet holder engages both the internal compression spring and the external compression spring.’ This statement has no support in the original disclosure.” (*Id.* at p. 5, para. 8). Although Applicants do not necessarily agree with the Examiner, Applicants have amended claims 10 and 13 in an effort to expedite prosecution. Applicants therefore submit that the rejection of claims 10-13, 15, 17, 19-

23, and 39 under 35 U.S.C. § 112, first paragraph, has been rendered moot, and request that the rejection be withdrawn.

### **III. 35 U.S.C. § 112, SECOND PARAGRAPH, REJECTION**

Claims 38 and 39 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. See Office Action, p. 6. Specifically, the Examiner asserts that “[c]laims 38 and 39 claim a sloped collar ramp and a cantilevered detent, it is unclear if applicant refers to another sloped ramp and detent or if the detent is cantilevered.” (*Id.* at p. 6, para. 10). Applicants submit that the rejection of claims 38 and 39 has been rendered moot by the amendments to claims 38 and 39. Applicants therefore request that the rejection of claims 38 and 39 under 35 U.S.C. § 112, second paragraph, be withdrawn.

### **IV. 35 U.S.C. § 103 REJECTIONS**

Applicants traverse the rejection of claims 1, 3, 5, 7, and 9 under 35 U.S.C. § 103(a) as being unpatentable over *Morita* in view of *Abulhaj*. Applicants respectfully disagree with the Examiner’s arguments and conclusions and submit that amended independent claim 1 patentably distinguishes over *Morita* and *Abulhaj* at least for the reasons described below.

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. See M.P.E.P. § 2142, 8th Ed., Rev. 7 (July 2008). Such an analysis should be made explicit and cannot be premised upon mere conclusory statements. See *id.* “A conclusion of obviousness requires that the reference(s) relied upon be enabling in that it put the

public in possession of the claimed invention.” M.P.E.P. § 2145. Furthermore, “[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art” at the time the invention was made. M.P.E.P. § 2143.01(III), internal citation omitted. Moreover, “[i]n determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.” M.P.E.P. § 2141.02(I), internal citations omitted (emphasis in original).

“[T]he framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). . . . The factual inquiries . . . [include determining the scope and content of the prior art and] . . . [a]scertaining the differences between the claimed invention and the prior art.” M.P.E.P. § 2141(II). “Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.” M.P.E.P. § 2141(III).

Amended independent claim 1 recites an adjustable nozzle assembly comprising: “an interior nozzle comprising a lancet wall, an assembly groove extending in a first direction, a ramped groove extending in a second direction deviating from the first direction, and a sloped mating ramp comprising a plurality of adjustment notches, the assembly groove being separated from the ramped groove by a raised boss; [and] a collar comprising a collar pin that engages the ramped groove and slides relative to the ramped groove, the collar being adapted to rotate relative to the interior nozzle; wherein

the collar pin is configured to slide through the assembly groove, over the raised boss, and into the ramped groove" (emphases added).

*Morita* appears to disclose an assembly for adjusting a pricking depth of a lancet including a cap element 3, an adjusting element 5, and a cover element 7. The cap element 3 includes a thread portion 17, and the adjusting element 5 includes a thread portion 53. The thread portion 53 is constructed such that it is engaged with a thread groove 47 of the thread portion 17 through a screw engagement mechanism. (*Morita*, col. 11, ll. 1-28 and col. 12, ll. 60-67).

As admitted by the Examiner, "*Morita* discloses the claimed invention except for the location of the notches and the detents, where the notches are in the collar and not in the interior nozzle and the detents are in the interior nozzle not on the collar." (*Office Action*, p. 8, ll. 5-7). The Examiner further admits "*Morita* does not disclose that the ramped groove is extending in a second direction deviating from the first direction in which the assembly groove extends." (*Id.* at p. 8, ll. 11-13). Additionally, the Examiner submits that "*Morita* in view of Abulhaj discloses the claimed invention except for the slope of the collar ramp and the slope of the mating ramp being approximately equal." (*Id.* at p. 10, ll. 1-2). *Morita* also fails to disclose "the assembly groove being separated from the ramped groove by a raised boss; . . . wherein the collar pin is configured to slide through the assembly groove, over the raised boss, and into the ramped groove" (emphases added), as recited in amended independent claim 1.

The Examiner alleges that "*Morita* discloses . . . a collar pin (53) that engages the ramped groove (47) and slides relative to the ramped groove . . . Furthermore, *Morita* discloses an assembly groove (the distal end of the groove 47 which is straight in one

portion), and that the collar pin (53) is configured to slide through the assembly groove to the ramped groove.” (*Office Action*, p. 7, ll. 1-17). The distal end of the thread groove 47 which is straight in one portion, which the Examiner equates to the claimed “assembly groove,” is not separated from the thread groove 47, which the Examiner equates to the claimed “ramped groove,” by a raised boss. Furthermore, the protruding portion 53, which the Examiner equates to the claimed “collar pin,” does not and cannot slide over a raised boss as it allegedly “first slides to the distal end of the groove which is the assembly groove and then slides down to where the groove is ramped which is the ramped groove.” (*Id.* at p. 7, ll. 17-19). Rather, when the protruding portion 53 of the adjusting element 5 engages the thread groove 47 of the cap element 3, the protruding portion 53 slides along the thread groove 47 in a screw-like, spiral-like fashion, rotating down towards the stop portion 37.

On the contrary, as disclosed on page 12, lines 14-17 of the specification of the present invention and illustrated in FIG. 9, “[n]ear where the assembly groove 66 meets the ramped groove 68, the interior nozzle 22 can comprise a raised boss 73. In assembly, the collar pin 51 can be slid in the assembly groove 66 and can then snap over the raised boss 73 into the ramped groove 68” (emphases added).

In order to cure the deficiencies of *Morita*, the Examiner relies on *Abulhaj* and alleges “*Abulhaj* discloses a lancet with an adjustable depth mechanism in which a cap (18) is adjustable by a pin/groove mechanism[,] . . . where the groove has an assembly groove . . . extending in a first direction . . . and a ramped groove . . . extending in a second direction.” (*Office Action*, p. 8, ll. 14-19). Such teaching, even if present in *Abulhaj*, however, does not constitute or suggest at least an adjustable nozzle

assembly, comprising: “the assembly groove being separated from the ramped groove by a raised boss; . . . wherein the collar pin is configured to slide through the assembly groove, over the raised boss, and into the ramped groove” (emphases added), as recited in amended independent claim 1.

Based on the Examiner’s interpretation of the claimed “assembly groove” and “ramped groove” in FIG. 16 of *Abulhaj* (see *Office Action*, p. 9), *Abulhaj* also fails to disclose the alleged assembly groove being separated from the alleged ramped groove by a raised boss. Rather, the two grooves appear to be connected and continuous from an opening in the helical recess 60 to an end of the helix 55. (*Abulhaj*, FIG. 16).

As explained above, the elements of independent claim 1 are neither taught nor suggested by the cited references. Consequently, the Office Action has neither determined the scope and content of the prior art nor ascertained the differences between the prior art and the claim. Accordingly, no reason has been clearly articulated as to why the claim would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 1. Claim 1, and claims 3, 5, 7, and 9 which depend therefrom, are patentable over *Morita* and *Abulhaj*. Applicants therefore request that the rejection of claims 1, 3, 5, 7, and 9 under 35 U.S.C. § 103(a) be withdrawn.

Applicants traverse the rejection of claims 10-12 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert*. Applicants respectfully disagree with the Examiner’s arguments and conclusions and submit that amended independent claim 10 patentably distinguishes over *Hofert* at least for the reasons described below.

Amended independent claim 10 recites a rearward body assembly of a lancing device comprising: “an interior tube comprising an open end and a slotted end through which the one or more retaining features extend, the interior tube slidably engaging the lancet holder; . . . a retainer comprising a slotted surface at a distal end of the interior tube through which the one or more retaining features extend; [and] a rearward body, the rearward body engaging the retainer and positioned externally around the periphery of the interior tube, wherein a distal end of the retainer is connected to a proximal end of the rearward body and a proximal end of the retainer is connected to the distal end interior tube” (emphases added).

*Hofert* appears to disclose a spring lancet holder for creating accurate standardized, reproducible puncture wounds in the skin for medical diagnostic purposes. (*Hofert*, Abstract). The spring lancet holder 10 includes a lancet 12 mounted within a collar 14, which is formed at one end of a blade guide 16, which is mounted for motion within a housing 18. The blade guide 16 may be moved vertically downward. Retarding this downward motion is a restoring spring 20. (*Id.* at col. 2, ll. 49-58).

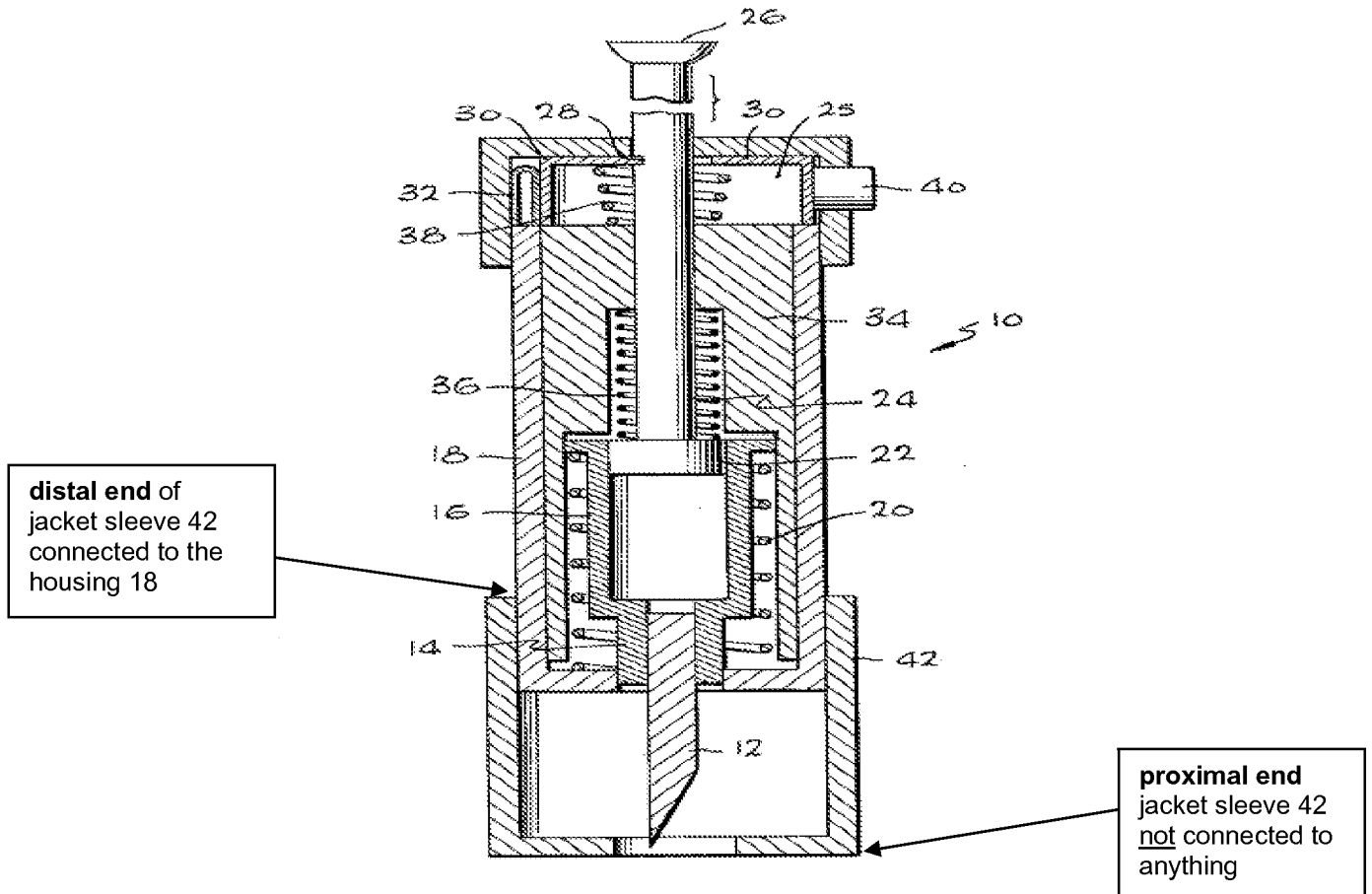
As admitted by the Examiner, *Hofert*, however, fails to teach or suggest at least “the rearward body is positioned around the periphery of the interior tube.” (*Office Action*, p. 13, ll. 15-16). *Hofert* also fails to disclose “wherein a distal end of the retainer is connected to a proximal end of the rearward body and a proximal end of the retainer is connected to the distal end interior tube.”

The Examiner alleges that *Hofert* discloses “an interior tube (34) comprising an open end (proximal end as seen in the Figure) and a slotted end (distal end where it is stepped and has an opening as seen in the Figure) through which one or more retaining



features extend . . . ; a retainer (42) comprising a slotted surface (opening where the finger collar enters) at the distal end of the interior tube . . . ; and a rearward body (combination of 24 and 22), the rearward body engaging the retainer (it is indirectly engaged to the retainer.” (*Office Action*, p. 11, line 12 - p. 12, line 17). Such teachings, even if disclosed in *Hofert*, which Applicants do not necessarily concede, however, fail to teach or suggest “wherein a distal end of the retainer is connected to a proximal end of the rearward body and a proximal end of the retainer is connected to the distal end interior tube,” as recited in amended independent claim 10.

A distal end of the jacket sleeve 42, which the Examiner equates to the claimed “retainer,” is not connected to a proximal end of striker plate 22 and the striker shaft 24, which the Examiner equates to the claimed “rearward body.” Further, a proximal end of the jacket sleeve 42 is not connected to a distal end of the mass 34, which the Examiner equates to the claimed “interior tube.” Rather, as illustrated below, the distal end of the jacket sleeve 42 is connected to the housing 18, and the proximal end of the jacket sleeve 42 is not connected to anything.



As explained above, the elements of independent claim 10 are neither taught nor suggested by the cited references. Consequently, the Office Action has neither determined the scope and content of the prior art nor ascertained the differences between the prior art and the claim. Accordingly, no reason has been clearly articulated as to why the claim would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 10. Claim 10, and claims 11 and 12 which depend therefrom, are patentable over *Hofert*. Applicants therefore request that the rejection of claims 10-12 under 35 U.S.C. § 103(a) be withdrawn.

Applicants traverse the rejection of claims 13, 15, 19, and 21-23 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert* in view of *Morita*, and further in view of *Abulhaj*. Applicants respectfully disagree with the Examiner's arguments and conclusions and submit that amended independent claim 13 patentably distinguishes over *Hofert*, *Morita*, and *Abulhaj* at least for the reasons described below.

Amended independent claim 13 recites a lancing device that can propel a lancet into a lancing surface, the lancing device, comprising: "an adjustable nozzle assembly through which the lancet can be propelled into a lancing surface, the adjustable nozzle assembly comprising: an interior nozzle comprising a lancet wall, an assembly groove extending in a first direction, a ramped groove extending in a second direction deviating from the first direction, and a sloped mating ramp comprising a plurality of adjustment notches, the assembly groove being separated from the ramped groove by a raised boss; [and] a collar comprising a collar pin that engages the ramped groove and slides relative to the ramped groove, the collar being adapted to rotate relative to the interior nozzle; wherein the collar pin is configured to slide through the assembly groove, over the raised boss, and into the ramped groove" (emphases added).

As discussed above, *Hofert* appears to disclose a spring lancet holder for creating accurate standardized, reproducible puncture wounds in the skin for medical diagnostic purposes. (*Hofert*, Abstract). The spring lancet holder 10 includes a lancet 12 mounted within a collar 14, which is formed at one end of a blade guide 16, which is mounted for motion within a housing 18. The blade guide 16 may be moved vertically downward. Retarding this downward motion is a restoring spring 20. (*Id.* at col. 2, ll. 49-58).

Further as discussed above, *Morita* appears to disclose an assembly for adjusting a pricking depth of a lancet including a cap element 3, an adjusting element 5, and a cover element 7. The cap element 3 includes a thread portion 17, and the adjusting element 5 includes a thread portion 53. The thread portion 53 is constructed such that it is engaged with a thread groove 47 of the thread portion 17 through a screw engagement mechanism. (*Morita*, col. 11, ll. 1-28 and col. 12, ll. 60-67).

As admitted by the Examiner, *Hofert*, however, “does not disclose an adjustable nozzle assembly.” (*Office Action*, p. 15, line 8). The Examiner further submits, “Hofert in view of *Morita* does not disclose that the ramped groove is extending in a second direction deviating from the first direction in which the assembly groove extends.” (*Id.* at p. 15, ll. 17-19).

Accordingly, in order to cure the deficiencies of *Hofert* and *Morita*, the Examiner relies on *Abulhaj* and alleges “*Abulhaj* discloses a lancet with an adjustable depth mechanism in which a cap (18) is adjustable by a pin/groove mechanism[,] . . . where the groove has an assembly groove . . . extending in a first direction . . . and a ramped groove . . . extending in a second direction.” (*Office Action*, p. 15, line 20 - p. 16, line 4). As discussed above, such teaching, even if present in *Abulhaj*, however, does not constitute or suggest at least a lancing device, comprising: “the assembly groove being separated from the ramped groove by a raised boss; . . . wherein the collar pin is configured to slide through the assembly groove, over the raised boss, and into the ramped groove” (emphases added), as recited in amended independent claim 13.

As explained above, the elements of independent claim 13 are neither taught nor suggested by the cited references. Consequently, the Office Action has neither

determined the scope and content of the prior art nor ascertained the differences between the prior art and the claim. Accordingly, no reason has been clearly articulated as to why the claim would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 13. Claim 13, and claims 15, 19, and 21-23 which depend therefrom, are patentable over *Hofert*, *Morita*, and *Abulhaj*. Applicants therefore request that the rejection of claims 13, 15, 19, and 21-23 under 35 U.S.C. § 103(a) be withdrawn.

Applicants traverse the rejection of claim 8 under 35 U.S.C. § 103(a) as being unpatentable over *Morita* in view of *Abulhaj*, and further in view of *Duchon*; and the rejection of claim 20 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert* in view of *Morita* and *Abulhaj*, and further in view of *Duchon*. The deficiencies of *Morita*, *Abulhaj*, and *Hofert* are discussed above.

With respect to *Duchon*, the Examiner alleges “*Duchon* discloses that the contact surface (48) is concave.” (*Office Action*, p. 11, ll. 4-5; p. 17, ll. 4-5). Such teaching, even if present in *Duchon*, however, does not constitute or suggest at least an adjustable nozzle assembly, comprising: “the assembly groove being separated from the ramped groove by a raised boss; . . . wherein the collar pin is configured to slide through the assembly groove, over the raised boss, and into the ramped groove” (emphases added), as recited in amended independent claim 1, and similarly amended independent claim 13.

Claims 8 and 20 correspondingly depend from independent claims 1 and 13 and require all elements thereof. As explained above, the elements of independent claims 1 and 13 are neither taught nor suggested by the cited references. Consequently, the Office Action has neither determined the scope and content of the prior art nor ascertained the differences between the prior art and the claims. Accordingly, no reason has been clearly articulated as to why the claims would have been obvious to one of ordinary skill in view of the prior art and a *prima facie* case of obviousness has not been established for claims 8 and 20 at least due to their dependence. Therefore, Applicants request that the rejection of claims 8 and 20 under 35 U.S.C. § 103(a) be withdrawn.

#### **V. CONCLUSION**

Applicants respectfully submit that claims 1, 3, 5, 7-13, 15, 17, and 19-23 are in condition for allowance.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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